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R.E.D. FACTS

CAPTAN

Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered before November 1, 1984, be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. To implement provisions of the Food Quality Protection Act of 1996 (FQPA), EPA considers the special sensitivity of infants and children to pesticides, as well as aggregate exposure of the public to pesticide residues from all sources, and the cumulative effects of pesticides and other compounds with common mechanisms of toxicity. The Agency develops any mitigation measures or regulatory controls needed to effectively reduce each pesticide's risks. EPA then reregisters pesticides that meet the safety standard of the FQPA and can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA explains the basis for its decision in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 0120, captan.

Use Profile

Captan is a fungicide used to control diseases on orchard crops, seed treatments, ornamentals, lawns and turf, and is also used as an in-can preservative in adhesives and paint. Formulations include dust, emulsifiable concentrate, flowable concentrate, water dispersible granules, wettable powder, and a variety of others.

Captan is applied by sprayers, chemigation equipment, power duster, liquid seed treater, paintbrush, tank-type sprayers, and other application methods. Captan is also applied as a post-harvest dip to apples, cherries and pears.

Regulatory History

Captan was first registered as a pesticide in the U.S. in 1951. EPA published the August 18, 1980 Notice of Rebuttable Presumption Against Reregistration (RPAR) because it had determined that captan exceeded certain risk criteria. The RPAR Notice was triggered by the Agency's receipt of data demonstrating that captan could induce oncogenic effects in experimental mammals (mice and rats).

The Agency issued a Registration Standard for captan in March 1986. The captan Registration Standard identified the data gaps required to be satisfied in order to continue the existing registration. A 1988 Data Call-In Notice required the submission of additional toxicity data.

EPA published the Position Document (PD4) "Captan; Intent To Cancel Registrations; Conclusion of Special Review" (54FR8116) on February 24, 1989. This notice announced the conclusion of EPA's Special Review and risk/benefit analysis of captan registrations. EPA evaluated additional data received and issues raised received during the Special Review process and decided to allow the continued registration of the following uses: all non-food uses, seed treatments, and certain food uses listed in the PD4 (almonds, apples, apricots, blackberries, blueberries, celery plant-beds, cherries, dewberries, eggplant plant-beds, grapes, green onions, lettuce, mangoes, nectarines, peaches, post-harvest pears, pepper plant-beds, pimento plant-beds, plums/prunes, raspberries, spinach plant-beds, strawberries, taro and tomato plant-beds). The Notice canceled all other uses.

Currently, 158 captan products are registered, of which nine are manufacturing-use products. Two technical registrants, Tomen Agro, Inc. and Makhteshim-Agan of North America, are members of the Captan Stewardship Task Force.

Human Health Assessment

Toxicity

The human health risk assessment evaluated toxicological and exposure data to develop dietary, drinking water, residential, aggregate and occupational exposure analyses, and to assess the adequacy of existing tolerances. Because the available studies demonstrated no indication of increased sensitivity of animals to *in utero* or postnatal exposure to captan and the database is complete, the Agency determined that there is no evidence of special sensitivity to infants and children. Therefore, the FQPA Safety Factor was removed (reduced to 1X) for captan and the RfD equals the PAD.

The developmental endpoint in rabbits, with a NOAEL of 10 mg/kg/day, was selected for the acute Reference Dose and the

short- and intermediate-term dermal risk assessments. A three-generation reproduction study in rats is the basis for the chronic RfD. The NOAEL in the study was 12.5 mg/kg/day. Captan is severely irritating to the eyes and is classified in the Toxicity Category I.

Captan is severely irritating to the eyes, and classified in Toxicity Category I based on corneal opacity in a rabbit study. Captan has been classified as a B2 probable human carcinogen, based on increased incidence of intestinal tumors in mice and rats. To estimate human cancer risks, the Agency used a linear, low dose extrapolation approach for captan. Based on intestinal tumors in mice, a Q1* of 2.4×10^{-3} $(mg/kg/day)^{-1}$ was calculated.

Dietary Exposure

EPA has assessed the acute and chronic dietary risk posed by captan, considering food and water sources of potential residues. Residues of captan plus the metabolite THPI were included in the anticipated residues for chronic (non-cancer) exposure and acute exposure in meat and milk.

To determine the risk from captan in foods, the Agency conducted acute, chronic (non-cancer) and chronic (cancer) dietary analyses. The acute analysis used a probabilistic dietary risk assessment estimated and the chronic dietary exposure was assessed using refinements such as anticipated residues and percent crop treated information. Since THPI is not considered carcinogenic, the cancer risk assessment considered only the residues of captan ***per se*****.**

The Agency has reassessed captan food and feed tolerances under the standards of FQPA. Crop group tolerances are being established for various groups of related vegetables. Many of these tolerances support seed treatment only, as the foliar applications have not been permitted since the PD4 was issued in 1989. The crop subgroup tolerance for caneberries (raspberries and blackberries) is being established to support Special Local Needs registrations in Oregon, Ohio, Pennsylvania, South Carolina, and Washington.

Occupational and Residential Exposure

For occupational risk, different routes of exposures are considered. As mentioned previously, captan is severely irritating to the eyes, and for dermal exposure, a dermal absorption rate of 0.4%/hour was selected. The assessments also assume that captan is taken up through the inhalation pathway to the same degree as oral ingestion.

Residential exposure to captan residues can occur by dermal and inhalation routes. Also, postapplication residential dermal exposure is expected from gardening and lawn activities on captan treated areas. The Agency is concerned about postapplication exposure to toddlers hand-to-mouth activity on treated lawns. The registrant has agreed to voluntarily cancel this use. Captan is also incorporated in paints and adhesives. Homeowner use of captan containing paints and adhesives do not result in a risk concern to the Agency.

Human Risk Assessment

The human health risk assessment evaluated toxicological and residue data, and included dietary, drinking water, aggregate, residential, and occupational exposure, as required by FQPA. The FQPA Safety Factor was removed as there is no evidence that there is increased sensitivity to infants and children from exposure to captan, and the database is complete for evaluating FQPA concerns.

An acute probabilistic dietary risk assessment estimated that acute dietary exposure to be 36% of the acute population adjusted dose (aPAD) at the 99.9th percentile. The chronic non-cancer dietary risk from exposure to captan is <2% of the chronic population adjusted dose (cPAD). The upper bound dietary cancer risk for the U.S. population is 1.3×10^{-7}, which is below the Agency's level of concern for lifetime excess cancer risk. The Agency has also determined that there is no risk concern from the consumption of captan residues in drinking water.

The Agency has also examined aggregate risk. These assessments take into account available information concerning exposures from the pesticide residue in food and all other exposures for which there is reliable information including pesticide residues in drinking water, exposure from pesticides uses in and around the home, and exposure in non-residential settings such as, parks and schools.

Residential exposure to captan may occur either during or after a captan application to home gardens, ornamental flowers, shrubs, or seeds. Exposure may also occur to golfers from treated golf courses. Because of concern about toddlers exposed to treated lawns, the technical registrants have agreed to voluntarily cancel these uses. For all other residential uses, exposure and risks do not exceed the Agency's level of concern.

The Agency has determined that acute and chronic dietary (food and water) and cancer aggregate risks are not of concern. Residential exposure from the use of captan around the home does not exceed the Agency's level of concern when aggregated with food and drinking water exposure.

For occupational scenarios, most risk estimates were well above 100 (values below 100 are a concern for captan) with cancer risks ranging from 1.3×10^{-5} to 1.7×10^{-9}. No additional mitigation is required to address occupational cancer risks. There is a concern for mixers and loaders of wettable powder for the aerial application of captan. The Agency believes that this risk will be adequately mitigated by requiring water soluble bags or a suitable reduction in application rate. Reentry Intervals were also reevaluated during the RED process and new REIs are being established ranging from 12-hours for seed treatment uses to 4-days for ornamentals.

The Agency is aware of a proposed common mechanism of carcinogenicity between captan and folpet, which implicates their common metabolite, thiophosgene. Because thiophosgene is so highly reactive in animal systems, its residues cannot be scientifically quantified. Without measurable residues of the common metabolite, it is difficult to relate exposures of captan to those of folpet since the rate of thiophosgene formation may be different for both compounds. The Agency has conducted a conservative aggregate assessment for thiophosgene, assuming that it may cause cancer through both captan and folpet, and has determined that this conservative risk is not of concern.

The FQPA also directed the Agency to develop an Endocrine Disruptor Screening Program, which was published in the Federal Register of December 28, 1998 (63 FR 71541). The Program uses a tiered approach and anticipates issuing a Priority List of chemicals and mixtures for Tier 1 screening in the year 2000. As the Agency proceeds with implementation of this program, further testing of captan and end-use products for endocrine effects may be required.

Environmental Assessment

Environmental Fate

Captan dissipates rapidly in the environment, with a half-life of less than 1 day, based on the results of hydrolysis and aerobic soil studies. Parent captan is slightly mobile to relatively immobile in various soils. The major degradates, THPI and THPAm, appear to be mobile in soil. Though these degradates have the potential to reach ground and surface water, they are not expected to be persistent.

Ecological Effects

For ecological risk, only acute toxicity to freshwater fish is of concern. There are no reported fish kills. Additionally, the Agency has determined that captan is: practically nontoxic to avian species, both on an acute and subacute basis; not acutely toxic to mammals,

and relatively nontoxic to insects. Terrestrial and aquatic plant toxicity is not a concern. Both THPI and THPAm were found to be non-toxic to fish species tested. The Agency is requiring a 96-hour oyster shell deposition study, however, these data are considered confirmatory and are not expected to change the conclusions of this risk assessment.

Risk Mitigation

To reduce the risks posed by captan, the Agency is requiring the following mitigation measures for captan-containing products:

- Voluntary cancellation of the residential turf use;
- Water-soluble packaging for the wettable powder formulation used aerially
- Various Personal Protective Equipment, including chemical-resistant gloves, aprons/coveralls, eye protection, and dust/mist respirators;
- Revised labeling to reduce the risks to non-target aquatic organisms;
- Eye wash stations for occupational field workers; and
- Double notification for workers entering treated fields.

Additional Data Required

EPA is requiring the following additional generic studies for captan to confirm its regulatory assessments and conclusions: the 96-hour oyster shell deposition study,72-3(b), Acute Estuarine/Marine Toxicity - Mollusk; 81-1 Acute Oral Toxicity (rat); 81-2 Acute Dermal Toxicity (rat/rabbit); 81-3 Acute Inhalation Toxicity (rat); 875.2400 Dermal Exposure; 875.2500 Inhalation Exposure; product-specific data including product chemistry, revised Confidential Statements of Formula (CSFs), and revised labeling for reregistration. These data are considered to be confirmatory and are not expected to change the conclusions of this RED.

Product Labeling Changes Required

All captan end-use products must comply with EPA's current pesticide product labeling requirements and with the following. For a comprehensive list of labeling requirements, please see Section V of the captan RED document.

Regulatory Conclusion

EPA has determined that products containing captan are eligible for reregistration, except for those with uses on turf and aerially-applied wettable powder formulations. Products applied to turf at sod farms or golf courses are eligible for reregistration; uses at all other turf sites are being voluntarily canceled. Wettable powder

formulations that are applied aerially are eligible for reregistration, provided either: 1) the products are packaged in water soluble packaging; or 2) the application rates are reduced to a level that is no higher than 1.2 lb ai/A. The use of eligible captan products in accordance with labeling specified in this RED will not pose unreasonable adverse effects to humans or the environment. These products will be reregistered once the required confirmatory generic data, product specific data, CSFs, and revised labeling are received and accepted by EPA. Products which contain active ingredients in addition to captan will be reregistered when all of their other active ingredients also are eligible for reregistration.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for captan during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Electronic copies of the RED and this fact sheet are available on the Internet. See http://www.epa.gov/REDs.

Printed copies of the RED and fact sheet can be obtained from EPA's National Center for Environmental Publications and Information (EPA/NCEPI), PO Box 42419, Cincinnati, OH 45242-2419, telephone 1-800-490-9198; fax 513-489-8695.

Following the comment period, the captan RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-605-6000.

For more information about EPA's pesticide reregistration program, the captan RED, or reregistration of individual products containing captan, please contact the Special Review and Reregistration Division (7508C), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticide Telecommunications Network (NPTN) toll-free at 1-800-858-7378. Their Internet address is ace.orst.edu/info/nptn.